68-9-3. Automated drug delivery system to supply drugs for administration in certain facilities. (a) Each of the following terms, as used in this regulation, shall have the meaning specified in this subsection:

(1) "Automated drug delivery system" means a robotic, mechanical, or computerized device that is used in a facility outside of a pharmacy for supplying drugs for administration.

(2) "Facility" means any of the following:

(A) A medical care facility, as defined in K.S.A. 65-1626 and amendments thereto;

(B) an institutional drug room, as defined in K.S.A. 65-1626 and amendments thereto; or

(C) a long-term care facility, which shall mean a nursing facility, as defined in K.S.A. 39-923 and amendments thereto.

(3) "Managing pharmacy" means a pharmacy located in Kansas.

(4) "Pharmacist-in-charge" means the pharmacist-in-charge of the managing pharmacy.

(b) Before the initial stocking and use of an automated drug delivery system to supply drugs for administration, the pharmacist-in-charge shall meet the following requirements:

(1) Provide the board with at least 14-day prior written notice, on a form provided by the board; and

(2) ensure that all necessary licenses, registrations, and authorizations, including a drug enforcement administration registration if supplying controlled substances, have been obtained.

(c) The pharmacist-in-charge shall consult with the pharmacy and therapeutics committee or an equivalent committee in establishing the criteria and process for determining a formulary of approved drugs that may be stored in the automated drug delivery system.

(d) A bar code verification, electronic verification, or similar verification process shall be utilized to ensure the correct selection of drugs placed or to be placed into each automated drug delivery system. The utilization of a bar code, electronic verification, or similar verification process shall require an initial quality assurance validation, followed by a quarterly assurance review by a pharmacist.

(e) The pharmacist-in-charge shall ensure that a policy exists requiring that if, at the time of loading any controlled substance, a discrepancy in the count of that drug in the automated drug delivery system exists, the discrepancy is immediately reported to the pharmacist-in-charge.

Whenever the pharmacist-in-charge becomes aware of a discrepancy regarding the count of a controlled substance in the automated drug delivery system, the pharmacist-in-charge shall be responsible for reconciliation of the discrepancy or proper reporting of the loss.

(f) The pharmacist-in-charge shall be responsible for the following:

(1) Controlling access to the automated drug delivery system;

(2) maintaining policies and procedures for the following:

(A) Operating the automated drug delivery system;

(B) providing prior training and authorization of personnel who are authorized to remove any drug from the automated drug delivery system;

(C) maintaining, at the location of the automated drug delivery system, a list of those individuals who are authorized to remove any drug from the automated drug delivery system;

(D) maintaining patient services whenever the automated drug delivery system is not operating; and

(E) defining a procedure for a pharmacist to grant access to the drugs in the automated drug delivery system;

(3) securing the automated drug delivery system;

(4) ensuring that each patient receives the pharmacy services necessary for appropriate pharmaceutical care;

(5) ensuring that the automated drug delivery system maintains the integrity of the information in the system and protects patient confidentiality;

(6) ensuring compliance with all requirements for packaging and labeling each medication pursuant to K.A.R. 68-7-15 and K.A.R. 68-7-16, unless the medication is already packaged in the manufacturer's sealed original container or in repackaged containers;

(7) ensuring that a system of preventive maintenance and sanitation exists and is implemented for the automated drug delivery system;

(8) ensuring that a policy exists for securing and accounting for all drugs that are wasted or discarded from the automated drug delivery system;

(9) ensuring that inspections are conducted and documented at least monthly to ensure the accuracy of the contents of the automated drug delivery system; and

(10) ensuring the accurate loading and unloading of the automated drug delivery system by approving and implementing an operational policy that limits the personnel responsible for the loading and unloading of the automated drug delivery system to a Kansas-licensed pharmacist or either of the following, each of whom shall be under the supervision of a Kansas-licensed pharmacist:

(A) A Kansas-registered pharmacy intern; or

(B) a Kansas-registered pharmacy technician.

(g) A pharmacist shall comply with the medication order review and verification requirements specified in K.A.R. 68-7-11.

(h) Except in the event of a sudden and unforeseen change in a patient's condition that presents an imminent threat to the patient's life or well-being, any authorized individual at a facility may distribute patient-specific drugs utilizing an automated drug delivery system without verifying each individual drug selected or packaged by the automated drug delivery system only if both of the following conditions are met:

(1) The initial medication order has been reviewed and approved by a pharmacist.

(2) The drug is distributed for subsequent administration by a health care professional permitted by Kansas law to administer drugs.

(i) The pharmacist-in-charge shall be responsible for establishing a continuous quality improvement program for the automated drug delivery system. This program shall include written procedures for the following:

(1) Investigation of any medication error related to drugs supplied or packaged by the automated drug delivery system;

(2) review of any discrepancy or transaction reports and identification of patterns of inappropriate use of or access to the automated drug delivery system; and

(3) review of the operation of the automated drug delivery system.

(j) The pharmacist-in-charge shall ensure that the managing pharmacy maintains, in a readily retrievable manner and for at least five years, the following records related to the automated drug delivery system:

(1) Transaction records for all drugs or devices supplied by the automated drug delivery system; and

(2) any report or analysis generated as part of the continuous quality improvement program.

(k) A Kansas-registered pharmacy technician or a Kansas-registered pharmacy intern who the pharmacist-in-charge has determined is properly trained may be authorized by that pharmacist-in-charge to perform the functions of loading and unloading an automated drug delivery system utilizing a bar code verification, electronic verification, or similar verification process as specified in subsection (d).

(l) If any drug has been removed from the automated drug delivery system, that drug shall not be replaced into the automated drug delivery system unless either of the following conditions is met:

(1) The drug's purity, packaging, and labeling have been examined according to policies and procedures established by the pharmacist-in-charge to determine that the reuse of the drug is appropriate.

(2) The drug is one of the specific drugs, including multidose vials, that have been exempted by the pharmacy and therapeutics committee or an equivalent committee.

(m) Upon the removal of any automated drug delivery system, the pharmacist-in-charge shall provide the board with notification, on a form provided by the board. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2015 Supp. 65-1637, K.S.A. 2015 Supp. 65-1642, and K.S.A. 65-1648; effective P-_____.)